



STEP-BD is a long-term program that aims to improve treatment and outcomes for people with bipolar disorder. By learning about your experience with bipolar disorder, your treatment response, and your quality of life during treatment, STEP-BD researchers can help you design a plan for managing your illness that works best for you. At the same time, your participation in STEP-BD will help improve treatment standards for the more than 2 million other Americans with bipolar disorder.

HOW CAN I PARTICIPATE?

If you are interested in participating in a study committed to improving the treatment of patients with bipolar disorder, please contact us at the Portland VA Medical Center/ OHSU by calling Robert Socherman at **503-220-8252 ext. 54522**. With your help, we hope to develop new strategies for treatment of bipolar depression and relapse prevention. Additionally, we hope to answer many important questions related to quality of life and economic outcomes.

FREQUENTLY ASKED QUESTIONS AND ANSWERS~

Q: What is the Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD)?

A: STEP-BD is the largest treatment study ever conducted for bipolar disorder. It is a long-term outpatient study (5 years) that aims to find out which treatments, or combinations of treatments, are most effective for treating episodes of depression and mania and for preventing recurrent episodes. While many treatments are used currently for bipolar disorder, including medications and psychotherapies, doctors are uncertain which of these treatments actually work best. Findings from STEP-BD will help improve the treatment standards used by doctors in everyday clinical practice.

Q: How is STEP-BD different from other treatment studies of bipolar disorder?

A: STEP-BD differs from traditional clinical trials in several ways. The main goal of STEP-BD is to improve treatment and outcomes for all people with bipolar disorder. It is a large-scale public health study that seeks to include people from diverse backgrounds living in communities throughout the United States. STEP-BD has very few exclusion criteria and welcomes individuals with co-occurring mental or physical illnesses. In addition to measuring improvement in illness symptoms, STEP-BD will evaluate how treatments influence other important issues such as quality of life, ability to work, and social functioning. The study also will assess the cost-effectiveness of different treatments and factors that affect how well people stay on their treatment plans. STEP-BD is unusual in that it offers participants long-term continuity of care. Participants will be followed and treated in a consistent manner throughout their involvement in the study, even when they are feeling well. In addition, STEP-BD studies most treatments currently used for bipolar

disorder, including medications and "talk" therapies, to determine the best ways to manage the illness over time. In more traditional clinical trials, individuals participate only for a limited time and have limited treatment options.

Q: Who is funding STEP-BD?

A: STEP-BD is funded by the National Institute of Mental Health (NIMH). NIMH, one of the 25 components of the National Institutes of Health (NIH), is the U.S. Government's principal agency for research on mental disorders, the brain, and behavior. NIH is part of the U.S. Department of Health and Human Services.

Q: Who can participate in STEP-BD?

A: Almost anyone who is age 18 or older and has a DSM-IV diagnosis of Bipolar Disorder or Cyclothymic Disorder (a less severe illness similar to bipolar disorder) can participate in STEP-BD. STEP-BD includes individuals who have more than one mental disorder diagnosis (for example, anxiety disorders or personality disorders) and those with physical illnesses. Individuals younger than age 18 need permission from a parent or legal guardian to participate. STEP-BD will enroll approximately 5,000 participants. Participation is entirely voluntary - people are always free to leave the study

Q: Where is the study being conducted?

A: STEP-BD is being conducted at research centers around the United States. Currently there are 17 sites in operation, and up to two more may be added for a total of 20 sites. Massachusetts General Hospital (Boston, MA) and the University of Pittsburgh School of Medicine (Pittsburgh, PA) are the coordinating centers for the study. The current site locations are: Stanford University (Stanford, CA) University of Colorado (Denver, CO) Rush-Presbyterian St. Luke's Medical Center (Chicago, IL) University of Louisville (Louisville, KY) Massachusetts General Hospital (Boston, MA) University of Massachusetts (Worcester, MA) University of Missouri (Kansas City, MO) State University of New York - Buffalo (Buffalo, NY) Cornell University - New York Presbyterian Hospital (New York, NY) New York University (New York, NY) Case Western Reserve University (Cleveland, OH) University of Oklahoma (Tulsa, OK) University of Pittsburgh (Pittsburgh, PA) University of Pennsylvania (Philadelphia, PA) Baylor College of Medicine (Houston, TX) University of Texas - San Antonio (San Antonio, TX), and Portland VA Medical Center/ Oregon Health and Science University (Portland, Oregon).

Q: Who is responsible for participants' treatment?

A: Participants receive treatment from psychiatrists who are specially trained in the treatment of bipolar disorder based on current best-practice guidelines. Seventy-five to 100 psychiatrists are involved in STEP-BD across the country. Clinical specialists at each STEP-BD site assist the doctors in monitoring each participant's progress.

Q: Which treatments are being studied?

A: STEP-BD is evaluating all the best-practice treatment options used for bipolar disorder: mood-stabilizing medications, antidepressants, atypical antipsychotics, monoamine oxidase inhibitors, and psychosocial interventions - or "talk" therapies - including cognitive behavioral therapy, family-focused therapy, interpersonal and social rhythm therapy, and psychoeducation.

Q: What is the treatment process in STEP-BD?

A: There are two kinds of treatment "pathways" in STEP-BD, and participants may have the opportunity to take part in both. The medications and psychosocial interventions provided in these pathways are considered among the best choices of treatment for bipolar disorder in everyday clinical practice.

In the "Best Practice Pathway," participants are followed by a STEP-BD certified doctor and all treatment choices are individualized. Everyone enrolled in STEP-BD may participate in this pathway. Participants and their doctors work together to decide on the best treatment plans and to change these plans if needed. Also, anyone who wishes to stay on his or her current treatment upon entering STEP-BD may do so in this pathway.

Another way to participate is in the STEP-BD "Randomized Care Pathways." Depending on their symptoms, participants may be offered treatment in one or more of these pathways during the course of the study. The participants remain on mood-stabilizing medication. However, because doctors are uncertain which of several treatment strategies work best for bipolar disorder, another medication and/or talk therapy may be added. Each Randomized Care Pathway involves a different set of these additional treatments.

Unlike in the Best Practice Pathway, the participants in the Randomized Care Pathways are randomly assigned to treatments. Also, in some cases, neither the participant nor the doctor will be told which of the different medications is being added. This is called a "double-blind" study and is done so that the medication effects can be evaluated objectively, without any unintended bias that may come from knowing what has been assigned. Participants will not be assigned medications that they have had bad reactions to in the past, that they are strongly opposed to, or that the doctor feels are unsuitable for them. There are other treatment options for participants if they do not respond well to the treatment assigned to them. Also, participants may return to the Best Practice Pathway at any time. About 1,500 individuals will be enrolled in at least one Randomized Care Pathway during their period of participation in STEP-BD.

It is important to note that STEP-BD provides continuity of care. For example, if a participant starts out in the Best Practice Pathway and later chooses to enter one of the Randomized Care Pathways, he or she continues with the same STEP-BD doctor and treatment team. Then, after completing the Randomized Care Pathway, the participant may return to the Best Practice Pathway for ongoing, individually-tailored treatment.

Q: Does STEP-BD use placebos?

A: Participants in STEP-BD will receive active medication throughout the study. No one will be given placebos (sugar pills) alone. However, those who participate in the Randomized Care Pathways of STEP-BD may receive pill placebos in combination with a mood stabilizer. For example, one question STEP-BD is attempting to answer is whether a mood stabilizer plus an antidepressant medication is more effective than a mood stabilizer alone for relieving an episode of depression in people with bipolar disorder. In this Randomized Care Pathway, participants are assigned to receive either the mood stabilizer plus an antidepressant, or the mood stabilizer plus placebo. Hence, placebos may be used in STEP-BD, but participants never go "medication-free."

Q: Are any "experimental" drugs being used?

A: The medications prescribed in STEP-BD are fully approved by the U.S. Food and Drug Administration (FDA) for use in people, and most are in common clinical use. The only exception is inositol, a special type of glucose that is a naturally-occurring substance. One of the Randomized Care Pathways in STEP-BD includes inositol, which is added to a mood stabilizer to evaluate its benefit for refractory depression.

Q: What do participants have to do in the study? How much time is involved?

A: After completing informed consent procedures, participants will be asked to fill out a set of intake forms and undergo a comprehensive medical and psychiatric evaluation by a STEP-BD doctor. Throughout their involvement in the study, participants will meet with their STEP-BD doctor for periodic evaluations and/or treatment adjustments. These visits may be more frequent earlier in the study or when a new treatment is added. Participants also will complete various self-rating forms during the study. However, participants can decline to answer any questions and can remain in the study even if their participation is inconsistent. Those involved in Randomized Care Pathways may be assigned to a psychosocial treatment that will require them to attend sessions lasting about an hour each. Overall, the estimated time commitment for participants is two to four hours per month.

Q: How long does the study last?

A: STEP-BD is designed to manage and evaluate participants' long-term treatment outcome. The project is currently funded for five years, and participants may be involved as long as they like during this time. Participants in any Randomized Care Pathway who respond well to their treatment will be asked to stay on it for up to 6 months (the actual time varies for different treatments). Subsequently, they may return to the Best Practice Pathway for continued individualized treatment and monitoring.

Q: Does participation in STEP-BD cost anything?

A: Participation in STEP-BD may not cost any more than usual care for bipolar disorder. Participants need to pay for treatment as they do currently - for example, through their insurance company or third-party payer. Free study medication is provided to those enrolled in Randomized Care Pathways. Funding to defray the cost of uninsured psychosocial treatments is available, based on need.

Q: What are the primary benefits of participating in STEP-BD?

A: There are a number of benefits to participating in STEP-BD. These include:

- Continuity of care - followed and treated by the same doctor throughout the study
- Individualized treatment by specially-trained, medical experts
- Long-term involvement in the program (5 years)
- Very few exclusion criteria
- No placebo-only treatment
- Thorough formal evaluation and monitoring
- Access to current best-practice treatments for bipolar disorder, including medications and psychosocial treatments
- Access to doctors who receive ongoing training and the latest information available about new and existing treatments

- Some treatments provided free or at reduced cost
- Ability to learn more about bipolar disorder
- Partnering with physicians to improve the standards of care for all people with bipolar disorder.

Q: What safeguards for participants does STEP-BD provide?

A: STEP-BD includes built-in safeguards to describe clearly and minimize risks to participants. Most importantly, STEP-BD emphasizes continuity of care. This allows the doctors and clinical specialists to carefully monitor participants' progress and changes in symptoms. If a participant gets worse or does not respond to one treatment, there are other options that can be offered in either the Best Practice Pathway or the Randomized Care Pathways (if applicable). Any participants in need of supervised inpatient care will be admitted to the hospital, and their STEP-BD doctor will continue to work with them to stabilize their symptoms.

Q: How can someone get more information about STEP-BD?

A: For more information about STEP-BD at the Portland VA Medical Center and OHSU, call Robert at **503-220-8252 ext. 54522** For more information about the national STEP-BD program, call toll-free **1-866-398-7425** or visit the STEP-BD [web page www.stepbd.org](http://www.stepbd.org).